DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 24, 2015

Dentis Co., Ltd.
% April Lee
Consultant
WithUS Consulting
2531 Pepperdale Drive
Rowland Heights, California 91748

Re: K150344
Trade/Device Name: Dentis Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 22, 2015
Received: June 26, 2015

Dear April Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Dentis Co., Ltd.
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Tel : 82.53.582.2804 / Fax : 82.53.583.2806

Indication for Use

510(K) Number (if known): K150344

Device Name: Dentis Dental Implant System

Indication for Use:

The Dentis Dental Implant System is an endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splinted interforminal placed implants.

Prescription Use ____X_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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510(k) Summary

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Device Information

- Trade Name: Dentis Dental Implant System
- Common Name: Dental Implant System
- Classification Name: Endosseous Dental Impant
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date prepared: 7/24/2015

General Description

An endosseous dental implant is a device made of Pure Titanium Grade 4. Dentis Dental Implant system has been designed to accommodate the following dental implant restoration protocols; Immediate or Early loading, immediate placement or one or two stage placement. Dentis Dental Implant systems help patients who have partial or whole teeth loss mastication to chew as dental implant. The surface of the system has been treated with RBM (Resorbable Blasted media). The fixture diameters are 3.7, 4.1, 4.3, 4.8mm and lengths are 7, 8, 10, 12, 14 mm in this system.

- s-Clean tapered fixture:
  Ø 3.7mm (D) x 7 mm (L) / 14 mm (L)
  Ø 4.1mm (D) x 7 mm (L) / 8 mm (L) / 10 mm (L) / 12 mm (L) / 14 mm (L)
  Ø 4.3mm (D) x 7 mm (L)
  Ø 4.8mm (D) x 7 mm (L)

The contained various abutments in the system are click bridge, cover screw, gold cylinder, solid abutment, couple abutment, angled abutment, healing cap, abutment screw, retaining screw, temporary cylinder, CCM cylinder, and connector.

The rage of the abutment diameters is 1.96 mm to 7.4mm and range of abutment lengths is 3.7mm to 14.25mm. The Connector, MU (Solid, couple, angled, abutment screw), MU Healing cap, and MU Retaining Screw are made of Ti-6Al-4V ELI. The MU click bridge body and MU Temporary Cylinder are made of Titanium Grade 4. The MU Click Bridge Cap is made of PEEK. The MU Gold Cylinder (Body) is made of Gold Alloy. The MU Gold Cylinder (Plastic Sleeve) and MU CCM Cylinder (Plastic Sleeve) are made of Acetal. The MU CCM Cylinder (Body) is made of Co-Cr-Mo alloy.

The possible angulation range of angled abutments is 17 to 30 degrees.

- Cover Screw
  Ø 3.6 mm (D) x 5.9 mm (L)
- MU Click Bridge Body
  Ø 4.8 mm (D) x 5.5 mm (L)
- MU Click Bridge Cap
  Ø 4.6 mm (D) x 4.8 mm (L)
- MU Gold Cylinder
  Ø 4.8 mm (D) x 14.25 mm (L)
- MU Solid Abutment
  Ø 4.8 mm (D) x 9.2 mm (L) / 10.2 mm (L) / 11.2 mm (L) / 12.2 mm (L)
- MU Couple Abutment
  Ø 4.8 mm (D) x 4.34 mm (L) / 5.34 mm (L) / 6.34 mm (L) / 7.34 mm (L)
- MU Angled Abutment
  Angle 17° - Ø 4.8 mm (D) x 6.08 mm (L) / 8.08 mm (L)
  Angle 30° - Ø 4.8 mm (D) x 6.69 mm (L) / 8.69 mm (L)
- MU Healing Cap
  Ø 5.4 mm (D) x 5.0 mm (L)
- MU Abutment Screw (Couple)
  Ø 1.96 mm (D) x 9.2 mm (L) / 10.2 mm (L) / 11.2 mm (L) / 12.2 mm (L)
- MU Abutment Screw (Angled)
  Ø 2.32 mm (D) x 7.8 mm (L)
- MU Retaining Screw
  Ø 1.98 mm (D) x 3.7 mm (L)
- MU Temporary Cylinder
  Ø 4.8 mm (D) x 10.0 mm (L)
- MU CCM Cylinder
  Ø 4.8 mm (D) x 14.25 mm (L)
- Connector
  Ø 5.7 mm (D) x 6.7 mm (L)
  Ø 3.8 mm (D) x 6.8 mm (L) / 6.0 mm (L)
  Ø 4.5 mm (D) x 6.85 mm (L) / 6.0 mm (L)
  Ø 5.4 mm (D) x 6.85 mm (L) / 6.0 mm (L)
  Ø 4.0 mm (D) x 8.7 mm (L) / 8.0 mm (L)
  Ø 4.3 mm (D) x 8.7 mm (L) / 8.0 mm (L)
  Ø 3.8 mm (D) x 9.0 mm (L) / 7.45 mm (L)
  Ø 4.2 mm (D) x 10.1 mm (L) / 7.95 mm (L)
  Ø 5.3 mm (D) x 5.15 mm (L), Ø 4.8 mm (D) x 4.45 mm (L)
  Ø 7.4 mm (D) x 6.85 mm (L) / 5.0 mm (L)
  Ø 5.3 mm (D) x 6.4 mm (L) / 5.7 mm (L)

The Fixtures are supplied sterile and the abutments are provided non-sterile. The abutments should be sterilized before use.

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Indication for Use

The Dentis Dental Implant System is an endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splinted interforminal placed implants.

Materials:

The devices are fabricated from CP Titanium (Grade 4) that conforms to ASTM F67 for Dental Implant and Titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136 for Abutments.

Performance Data (Bench Testing):

Non-clinical tests followed the recommendations in the "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant abutments". Fatigue Testing performed in accordance with ISO 14801:2007 under the worst case scenario, Sterilization Validation testing performed in accordance with ISO 11137-1:2006, ISO 11137-2:2006 and biocompatibility evaluation by comparing materials and manufacturing process with the predicate device, and surface treatment analysis were used to support the decision of substantial equivalence.

Predicate Devices:

The subject device is substantially equivalent to the following predicate device:

- K073486, Dentis Dental Implant System manufactured by Dentis Co., Ltd.

Comparison to Predicate Device:

1) Fixture

	Subject device	Predicate device
Device name	Dentis Dental Implant System	Dentis Dental Implant System
510(k) number	NA	K073486
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.
Intended use	Identical to predicate devices	DENTIS implant is designed for use in edentulous sites in the mandible or maxilla for support for a complete denture prosthesis, terminal or intermediate abutment for fixed

		bridgework, partial dentures, or single tooth replacements.
Material	Commercially pure titanium GR.4 (ASTM-F-67)	Commercially pure titanium GR.3 and GR.4 (ASTM-F-67)
Design	Morse Taper with Tread	Morse Taper with Tread
Fixture diameter	3.7, 4.1, 4.3, 4.8mm	3.5, 3.7, 4.1, 4.3, 4.8, 5.5, 6.0mm
Fixture length	7-14mm	7-14mm
Surface treatment	RBM	RBM
Gamma sterilized	Yes	Yes
Product Code	DZE	DZE

2) Abutment

	Subject device	Predicate device
510(k) number	NA	K073486
Product Name	**Cover Screw**	Cover Screw
Dimension	Ø 3.6 mm (D) x 5.9 mm (L)	Ø 3.4 mm (D) x 6.5 mm (L)
Material	CP Titanium Grade 4	Ti-6Al-4V ELI
Connection	Hex Type	Hex Type
Product Name	**MU Click Bridge Body, Cap**	N/A
Dimension	(Body) Ø 4.8 mm (D) x 5.5 mm (L) (Cap) Ø 4.6 mm (D) x 4.8 mm (L)	N/A
Material	(Body) CP Titanium Grade 4 (Cap) PEEK	N/A
Product Name	**MU Gold Cylinder**	i-Clean Gold Cylinder
Dimension	Ø 4.8 mm (D) x 14.25 mm (L)	Ø 5.0 mm (D) x 14.3 mm (L)
Material	(Body) Gold Alloy (Plastic Sleeve) Acetal	(Body) Gold Alloy (Plastic Sleeve) Acetal
Product Name	**MU Solid Abutment**	s-Clean Sole Abutment
Dimension	Ø 4.8 mm (D) x 9.2 / 10.2 / 11.2 / 12.2 mm (L)	Ø 4.5 / 5.5 / 6.5 mm (D) x 5.5 mm (L)
Material	Ti-6Al-4V ELI	CP Titanium Grade 4
Product Name	**MU Couple Abutment**	s-Clean Couple Abutment
Dimension	Ø 4.8 mm (D) x 4.34 / 5.34 / 6.34 / 7.34 mm (L)	Ø 4.5 / 5.5 / 6.5 mm (D) x 5.0 / 7.0 mm (L)

Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Connection	Hex Type	Hex / Non-Hex Type
Product Name	**MU Angled Abutment**	N/A
Dimension	Ø 4.8 mm (D) x 6.08 / 8.08 / 6.69 / 8.69 mm (L)	N/A
Angle	17°, 30°	N/A
Material	Ti-6Al-4V ELI	N/A
Connection	Hex Type	N/A
Product Name	**MU Healing Cap**	s-Clean Sole Abutment Healing Cap
Dimension	Ø 5.4 mm (D) x 5.0 mm (L)	Ø 4.5 / 5.5 / 6.5 mm (D) x 4.0 mm (L)
Material	Ti-6Al-4V ELI	Acetal
Product Name	**MU Abutment Screw**	Abutment Screw
Dimension	(1) Ø 1.96 mm (D) x 9.2 mm (L) / 10.2 mm (L) / 11.2 mm (L) / 12.2 mm (L) (2) Ø 2.32 mm (D) x 7.8 mm (L)	Ø 2.32 mm (D) x 9.8 mm (L)
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Product Name	**MU Retaining Screw**	N/A
Dimension	Ø 1.98 mm (D) x 3.7 mm (L)	N/A
Material	Ti-6Al-4V ELI	N/A
Product Name	**MU Temporary Cylinder**	i-Clean Temporary Abutment
Dimension	Ø 4.8 mm (D) x 10.0 mm (L)	Ø 5.0 mm (D) x 11.5 mm (L)
Material	CP Titanium Grade 4	CP Titanium Grade 4
Product Name	**MU CCM Cylinder**	N/A
Dimension	Ø 4.8 mm (D) x 14.25 mm (L)	N/A
Material	(Body) Co-Cr-Mo Alloy (Plastic Sleeve) Acetal	N/A
Product Name	**Connector**	N/A
Dimension	3.8~7.4 mm (D) x 5.0~10.1 mm (L)	N/A
Material	Ti-6Al-4V ELI	N/A
Sterilization	Steam sterilization by user	Steam sterilization by user
Product Code	NHA	NHA

Substantial Equivalence Discussion

The Dentis Dental implant System has a substantially equivalent intended use as the identified predicate. The subject device is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutment, and they are all constructed of titanium.

The subject and predicate device are similar in indications, design, technology, functions, dimensions and materials.

The differences between the subject and predicate devices are the addition of the 7mm and 14 mm of the fixtures and various abutments to this subject device.

Conclusion

The Dentis Dental Implant System, subject device of this submission, constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, Dentis Dental Implant System and its predicate are substantially equivalent.